IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS **EASTERN DIVISION**

The estate of CHRISTIE SCOTT,)	
Plaintiff,)	
vs.)	
)	Case No. 08-CV-3549
SANOFI-AVENTIS,)	
SANOFI-AVENTIS U.S. INC.,)	
SANOFI-SYNTHELABO,)	
SANOFI-SYNTHELABO, INC.,)	
)	
Defendants.)	

DEFENDANTS SANOFI-AVENTIS U.S. INC. AND SANOFI-SYNTHELABO INC.'S ANSWER TO PLAINTIFF'S COMPLAINT AT LAW

NOW COME Defendants sanofi-aventis U.S. Inc. and Sanofi-Synthelabo Inc. (incorrectly named in the caption as "Sanofi-Synthelabo, Inc.") (collectively, the "Answering Defendants"¹), by and through undersigned counsel, and for their answer to Plaintiff's Complaint at Law ("Plaintiff's Complaint") state as follows:

1. Sanofi-Aventis is a corporation organized and existing under the laws of France, and having its principal place of business at 174 Avenue de France, Paris, France, and is involved in the manufacture of the drug, Ambien.

Plaintiff served Sanofi-Synthelabo Inc. twice via its registered agent in Illinois. Plaintiff has also named "Sanofi-Synthelabo" as a defendant in this case. Sanofi-Synthelabo, a French corporation, took control of Aventis in 2004. Subsequently, Sanofi-Synthelabo changed its registered name to sanofi-aventis. On December 31, 2004, Aventis formally merged with and into sanofi-aventis, with sanofi-aventis as the surviving company. Sanofi-aventis is a French corporation. Sanofi-aventis has not been served in this action.

ANSWER: The Answering Defendants admit sanofi-aventis, S.A. (hereinafter, "sanofi-aventis") is a corporation organized and existing under the laws of France. The Answering Defendants deny all remaining allegations in paragraph 1 of Plaintiff's Complaint.

2. Sanofi-Aventis U.S. Inc, and Sanofi-Synthelabo, Inc., manufacture the prescription drug Ambien.

ANSWER: The Answering Defendants admit that, at certain times, Sanofi-Synthelabo Inc. manufactured, distributed and sold Ambien® until 2005, for use by prescription only, through a licensed physician, in accordance with its FDA-approved prescribing information. The Answering Defendants deny all remaining and inconsistent allegations in paragraph 2 of Plaintiff's Complaint.

3. Sanofi-Aventis U.S., Inc. was the U.S. subsidiary of Sanofi-Aventis, and is a Delaware corporation licensed to do business within the State of Illinois, and is involved in the manufacture of the Drug, Ambien.

ANSWER: The Answering Defendants state that sanofi-aventis U.S. Inc. is a wholly-owned, indirect subsidiary of sanofi-aventis and is a Delaware corporation, licensed to do business in the State of Illinois. The Answering Defendants deny all remaining and inconsistent allegations in paragraph 3 of Plaintiff's Complaint.

4. On or about February 26, 2006, Sanofi-Synthelabo, Inc., was the U.S. subsidiary of Sanofi-Synthelabo, and is a Delaware corporation licensed to do business within the State of Illinois.

ANSWER: The Answering Defendants state that on or about February 26, 2006, Sanofi-Synthelabo Inc. was a wholly-owned, indirect subsidiary of sanofi-aventis. The Answering Defendants admit that Sanofi-Synthelabo Inc. is a Delaware corporation, licensed to do business in the State of Illinois. The Answering Defendants state that in August 2004, Sanofi-Synthelabo took control of Aventis and changed its registered name to sanofi-aventis. On December 31, 2004, Aventis merged with and into sanofi-aventis, with sanofi-aventis as the surviving company. The Answering Defendants deny all remaining and inconsistent allegations in paragraph 4 of Plaintiff's Complaint.

5. On or about February 26, 2006, Plaintiff, CHRISTIE SCOTT was taking the prescription medication Ambien.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 5 of Plaintiff's Complaint, and therefore deny them.

6. On or about February 26, 2006, after taking the medication, Ambien, which the Defendants manufactured, CHRISTIE SCOTT, was sleep walking and fell down a flight of stairs and died. The sleep walking and resultant death from her fall was proximately caused by the Ambien.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 6 of Plaintiff's Complaint regarding Christie Scott's use of Ambien® (zolpidem tartrate), and therefore deny them. The Answering Defendants deny all remaining allegations in paragraph 6 of Plaintiff's Complaint.

COUNT I NEGLIGENCE

7. Plaintiff hereby incorporates by reference each paragraph of this Complaint as though fully set forth herein.

ANSWER: The Answering Defendants incorporate by reference their responses in the above paragraphs as though fully set forth herein.

8. At all times material hereto, Defendants, designed, developed, manufactured, marketed, delivered and/or sold Ambien.

ANSWER: The Answering Defendants admit that, at certain times, Sanofi-Synthelabo Inc. designed, developed, manufactured, marketed, distributed and sold Ambien® until 2005, for use by prescription only, through a licensed physician, in accordance with its FDA-approved prescribing information. The Answering Defendants deny all remaining and inconsistent allegations in paragraph 8 of Plaintiff's Complaint.

9. At all times material hereto, Defendants knew or should have known that Ambien would be used by Plaintiff who would suffer the adverse side effects of sleepwalking.

ANSWER: The Answering Defendants deny the allegations in paragraph 9 of Plaintiff's Complaint.

10. At all times material hereto, Defendants designed, developed, manufactured, marketed, distributed and/or sold Ambien knowing, or through the exercise of reasonable care, should have known that it was defective and would damage the Plaintiff.

ANSWER: The Answering Defendants deny the allegations in paragraph 10 of Plaintiff's Complaint.

11. Defendants failed to warn, or adequately or sufficiently warn, either directly or indirectly, the foreseeable users of the potential hazards and costs associated with the use of Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 11 of Plaintiff's Complaint.

12. Defendants failed to adequately test Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 12 of Plaintiff's Complaint.

13. Defendants systematically failed to represent accurately to the Plaintiff, either directly or indirectly, that Ambien and its constituents can pose a health hazard and injure or cause death to persons by its adverse side-effects or that Ambien was defective.

ANSWER: The Answering Defendants deny the allegations in paragraph 13 of Plaintiff's Complaint.

14. Defendants systematically failed to monitor and investigate reported instances of sleepwalking resulting from the use of Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 14 of Plaintiff's Complaint.

15. Defendants systematically failed to train, warn or educate, or inadequately, trained, warned or educated the Plaintiff or their doctors of the signs and symptoms of adverse reactions of sleepwalking to the use of Ambien or that users of Ambien should be carefully observed for signs or symptoms of adverse side affects, even though it had a duty to do so.

ANSWER: The Answering Defendants deny the allegations in paragraph 15 of Plaintiff's Complaint.

16. Defendants failed to acknowledge responsibility for adverse side effects caused by Ambien, thereby contributing to the false impression cultivated by Defendants that Ambien is safe.

ANSWER: The Answering Defendants deny the allegations in paragraph 16 of Plaintiff's Complaint.

17. Defendants failed to represent accurately to Plaintiff, either directly or indirectly, that Ambien, used for its ordinary and intended purpose, can pose a health hazard and/or injure users, whereby Plaintiff was induced to purchase ambient [sic].

ANSWER: The Answering Defendants deny the allegations in paragraph 17 of Plaintiff's Complaint.

18. Defendants at all times failed and continue to fail to perform their duties to warn and recall.

ANSWER: The Answering Defendants deny the allegations in paragraph 18 of Plaintiff's Complaint.

19. Upon information and belief, Defendants' actions, as alleged, constitute violations of statutory and regulatory provisions.

ANSWER: The Answering Defendants deny the allegations in paragraph 19 of Plaintiff's Complaint.

20. Defendants' acts and omissions complained of in this count were committed by them with indifferent to the rights of the Plaintiff and were carried out to maximize the sale of Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 20 of Plaintiff's Complaint.

21. As a direct and proximate result of Defendants' conduct, Plaintiff suffered damage and death.

ANSWER: The Answering Defendants deny the allegations in paragraph 21 of Plaintiff's Complaint.

COUNT II STRICT LIABILITY

22. Plaintiff hereby incorporates by reference each paragraph of this Complaint, as though fully set forth herein.

ANSWER: The Answering Defendants incorporate by reference their responses in the above paragraphs as though fully set forth herein.

23. Defendants have been and are engaged in the business of designing, manufacturing, marketing, distributing and/or selling Ambien.

Page 8 of 22

ANSWER: The Answering Defendants admit that, at certain times, Sanofi-Synthelabo Inc. designed, manufactured, marketed, distributed and sold Ambien® until 2005, for use by prescription only, through a licensed physician, in accordance with its FDA-approved prescribing information. The Answering Defendants deny all remaining and inconsistent allegations in paragraph 23 of Plaintiff's Complaint.

24. Ambien, as used by Plaintiff was defective and unreasonably dangerous, unfit for its intended use because of the deleterious and highly harmful effects to caused to Plaintiff.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 24 of Plaintiff's Complaint regarding Plaintiff's use of Ambien® (zolpidem tartrate), and therefore deny them. The Answering Defendants deny all remaining allegations in paragraph 24 of Plaintiff's Complaint.

25. Defendants reasonably expected Ambien to be used by Plaintiff.

ANSWER: The Answering Defendants deny the allegations in paragraph 25 of Plaintiff's Complaint.

26. Plaintiff used Ambien in the manner in which was intended and exacted by Defendants. Upon information and belief, at the time of such use, Ambien had not been changed from the time it was designed, manufactured, marketed, distributed or sold by Defendants.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 26 of Plaintiff's Complaint regarding Plaintiff's use of Ambien® (zolpidem tartrate), and therefore deny them.

The Answering Defendants deny all remaining allegations in paragraph 26 of Plaintiff's Complaint.

27. As a direct and proximate cause of Plaintiff using Defendants defective and unreasonably dangerous product, Plaintiff has suffered damage and death.

ANSWER: The Answering Defendants deny the allegations in paragraph 27 of Plaintiff's Complaint.

COUNT III BREACH OF IMPLIED WARRANTIES

28. Plaintiff hereby incorporates by reference each paragraph in this Complaint, as if fully set forth herein.

ANSWER: The Answering Defendants incorporate by reference their responses in the above paragraphs as though fully set forth herein.

29. Defendants failed to represent accurately to Plaintiff, either directly or indirectly, that Ambien is unfit and unsafe to consumers with insomnia and other sleep related disorders.

ANSWER: The Answering Defendants deny the allegations in paragraph 29 of Plaintiff's Complaint.

30. Defendants intended Ambien to be used on persons suffering from insomnia, and implied warranted through the sale, advertising, and/or marketing of Ambien that it was fit for these normal and foreseeable uses.

ANSWER: The Answering Defendants admit that, at all times relevant to Plaintiff's Complaint, Ambien® (zolpidem tartrate) was approved by the FDA for the short term treatment

of insomnia and was available for use by prescription only, through a licensed physician, in accordance with its FDA-approved prescribing information. The Answering Defendants deny all remaining and inconsistent allegations in paragraph 30 of Plaintiff's Complaint.

31. Plaintiff as foreseeable and intended user of Defendant's product, relied upon Defendant's representations, skill, expertise and judgment in assuming that Ambien would not only perform its basic functions as warranted, but was safe, and would not have adverse side effects of sleep walking.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 of Plaintiff's Complaint regarding Plaintiff's reliance and use of Ambien® (zolpidem tartrate), and therefore deny them. The Answering Defendants deny all remaining allegations in paragraph 31 of Plaintiff's Complaint.

32. Defendant breached these implied warranties in that Ambien as designed, manufactured, marketed, distributed or sold is deleterious and highly harmful, and can and does injure persons and others as a result of their entering into a hypnotic state and sleep walking.

ANSWER: The Answering Defendants deny the allegations in paragraph 32 of Plaintiff's Complaint.

33. As a direct and proximate result of Defendants' breach of implied warranties of goods and merchantable quality and fitness for a particular purpose and for their intended use, Plaintiff suffered and was caused death.

ANSWER: The Answering Defendants deny the allegations in paragraph 33 of Plaintiff's Complaint.

COUNT IV FRAUD

34. Plaintiff hereby incorporates by reference each paragraph in this Complaint, as if fully set forth herein.

ANSWER: The Answering Defendants incorporate by reference their responses in the above paragraphs as though fully set forth herein.

35. Defendants at all times in designing, manufacturing, marketing, distributing and selling Ambien knew that this product was and is hazardous and/or potentially hazardous to consumers, and knew that it causes sleep walking.

ANSWER: The Answering Defendants deny the allegations in paragraph 35 of Plaintiff's Complaint.

36. At all times relevant in marketing their Ambien, Defendants falsely and fraudulently represented expressly or impliedly to Plaintiff, the public and the market that Ambien was safe. Defendants suppressed and concealed facts that Ambien could be harmful, dangerous and deleterious to consumers. Defendants knew of these dangerous propensities when it designed, manufactured, marketed and distributed and sold Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 36 of Plaintiff's Complaint.

37. Defendants at all times had a continuing duty to disclose the dangerous propensities of their product to Plaintiff, the public, and the market, and the suppression of these facts constituted misleading and fraudulent misrepresentations because Defendants published disseminated information such as publications and televised commercials representing Ambien would put a person to sleep and was well-suited, safe, and highly effective for its intended, use, and which were likely to mislead for want of communication of suppressed facts, including the hazardous nature and dangerous propensities of Ambien's side effects.

ANSWER: The Answering Defendants deny the allegations in paragraph 37 of Plaintiff's Complaint.

38. The misrepresentations, suppressions, and failures to disclose information were made by Defendants with the intent to induce Plaintiff, the public and the market to purchase and use Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 38 of Plaintiff's Complaint.

39. Plaintiff relied on Defendants' misrepresentations as well as the absence of adverse information in purchasing and using Ambien.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 39 of Plaintiff's Complaint regarding Plaintiff's reliance and use of Ambien® (zolpidem tartrate), and therefore deny them. The Answering Defendants deny all remaining allegations in paragraph 39 of Plaintiff's Complaint.

40. Defendants continued at all times relevant to falsely and fraudulently misrepresent, suppress, and fail to disclose the dangerous propensities of Ambien, including the fact that Ambien causes sleep walking.

ANSWER: The Answering Defendants deny the allegations in paragraph 40 of Plaintiff's Complaint.

41. Plaintiff at the times these failures to disclose and suppressions of fact occurred, and that the time of purchase and use of the product, were ignorant of the existence of the facts that Defendants misrepresented, suppressed and failed to disclose. If Plaintiff had been aware of the existence of the facts misrepresented or not disclosed by Defendants, Plaintiff would not have purchased or used Ambien, and would not have suffered the damages alleged herein.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 41 of Plaintiff's Complaint regarding Plaintiff's purchase and use of Ambien® (zolpidem tartrate), and therefore deny them. The Answering Defendants deny all remaining allegations in paragraph 41 of Plaintiff's Complaint.

42. As a direct and proximate result of Defendants suppression of facts and failure to disclose, and the continued manufacture, sale and marketing of Ambien, Plaintiff was directly and materially harmed.

ANSWER: The Answering Defendants deny the allegations in paragraph 42 of Plaintiff's Complaint.

43. All Defendants acts and omissions complained of in this count were committed by them with indifference of the rights of Plaintiff and were intentionally carried out to maximize the same and use of Ambien.

ANSWER: The Answering Defendants deny the allegations in paragraph 43 of Plaintiff's Complaint.

COUNT V EXPRESS WARRANTY

44. The Plaintiff hereby incorporates by reference each paragraph in this Complaint, as if fully set forth herein.

ANSWER: The Answering Defendants incorporate by reference their responses in the above paragraphs as though fully set forth herein.

45. At all times relevant, Defendants, in order to induce the Plaintiff to purchase and use Ambien, warranted and represented that its product was safe for its intended use for insomnia.

ANSWER: The Answering Defendants deny the allegations in paragraph 45 of Plaintiff's Complaint.

46. Plaintiff purchased and used Ambien in reliance on the Defendants' abovementioned warranties and representations.

ANSWER: The Answering Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 46 of Plaintiff's Complaint regarding Plaintiff's purchase and use of Ambien® (zolpidem tartrate), and therefore

deny them. The Answering Defendants deny all remaining allegations in paragraph 46 of Plaintiff's Complaint.

47. The Ambien distributed, sold and/or delivered to Plaintiff was not of a character as stated by Defendants, but was defective and deficient as it did not put Plaintiff to sleep but placed Plaintiff in a hypnotic state.

ANSWER: The Answering Defendants deny the allegations in paragraph 47 of Plaintiff's Complaint.

48. Upon information and belief, Defendants received due and proper notice.

ANSWER: The Answering Defendants deny the allegations in paragraph 48 of Plaintiff's Complaint.

49. As a result of the defective and deficient nature of Ambien, which is contrary to the warranties and representations of Defendants, the Plaintiff suffered damage and death.

ANSWER: The Answering Defendants deny the allegations in paragraph 49 of Plaintiff's Complaint.

The Answering Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been expressly admitted, denied, or explained.

ADDITIONAL DEFENSES

By asserting the following separate and affirmative defenses, Answering Defendants do not allege or admit they have the burden of proof and/or the burden of persuasion with respect to any of these matters:

- 1. Plaintiff's claims are barred by the applicable statutes of limitations and/or repose, including but not limited to those set forth in 735 ILCS § 13-202.
- 2. The methods, standards, and techniques utilized with respect to the manufacture, design, marketing, distribution and sale of Ambien® (zolpidem tartrate), if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.
- 3. The claims asserted in Plaintiff's Complaint are barred because Ambien® (zolpidem tartrate) was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.
- 4. The claims asserted in Plaintiff's Complaint, which regard the alleged use of Ambien® (zolpidem tartrate), a prescription medication, are barred in whole or in part by the "learned intermediary" doctrine.
- 5. If Plaintiff or Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by operation of nature or other supervening or intervening conduct of persons other than the Answering Defendants, and for whose conduct the Answering Defendants are not responsible, or with whom the Answering Defendants have no legal relation or legal duty to control.

- 6. If Plaintiff of Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by the negligence of Plaintiff or Plaintiff's decedent in failing to exercise due and proper care under the existing circumstances and conditions, and his alleged damages, if any, are barred or reduced by the doctrines of contributory or comparative negligence.
- 7. If Plaintiff or Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by the unforeseeable alterations, improper handling, or other unforeseeable misuse of Ambien® (zolpidem tartrate) by persons other than the Answering Defendants or persons acting on their behalf.
- 8. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Ambien® (zolpidem tartrate) was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.
- 9. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.
- 10. Plaintiff's claims are barred because his injuries or the injuries of Plaintiff's decedent, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff or Plaintiff's decedent, and were independent of or far removed from the Answering Defendants' conduct.
- 11. If Plaintiff or Plaintiff's decedent sustained any injuries or incurred any losses or damages as alleged in Plaintiff's Complaint, the same was caused by unforeseeable idiosyncratic reactions of Plaintiff's decedent.

- 12. Plaintiff's claims are barred by the doctrines contained in the Restatement (Second) Torts §402(A), Comment j, Restatement (Second) Torts §402(A), Comment k, and/or Restatement (Third) of Torts: Products Liability §§ 4 *et. seq.* and 6.
- 13. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Ambien® (zolpidem tartrate) did not proximately cause injuries or damages to Plaintiff or Plaintiff's decedent.
- 14. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate the Answering Defendants' rights under the United States Constitution.
- 15. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.
- 16. The claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Ambien® (zolpidem tartrate) were not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution.
- 17. The claims must be dismissed because Plaintiff's decedent would have taken Ambien® (zolpidem tartrate) even if the product labeling contained the information that Plaintiff contends should have been provided.
- 18. The claims asserted in Plaintiff's Complaint are barred because the utility of Ambien® (zolpidem tartrate) outweighed its risks.

- 19. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.
- 20. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.
- 21. The liability of the Answering Defendants, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's or Plaintiff's decedent's alleged injuries or damages, if any, are determined. The Answering Defendants seek an adjudication of the percentage of fault of the claimant and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff's decedent.
- 22. The Answering Defendants are entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiff with any other defendant or other person or entity subsequently joined to this action.
- 23. Plaintiff's claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et. seq.*, the regulations promulgated thereunder, and the United States Constitution, Article IV, clause 2.
- 24. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.
- 25. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in Plaintiff's Complaint.

26. The claims asserted in Plaintiff's Complaint are barred, in whole or in part, because Ambien® (zolpidem tartrate) is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated thereunder, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Ambien® (zolpidem tartrate). Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Case 1:08-cv-03549

- 27. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in Plaintiff's Complaint, such injuries or losses were only so sustained after Plaintiff or Plaintiff's decedent knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation sold by the Answering Defendants or other sellers.
- 28. If Plaintiff or Plaintiff's decedent has sustained injuries or losses as alleged in Plaintiff's Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of the Answering Defendants and over whom the Answering Defendants had no control and for whom the Answering Defendants may not be held accountable.
- 29. Plaintiff's claims are barred in whole or in part because Ambien® (zolpidem tartrate) "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

20

Case 1:08-cv-03549 Document 6 Filed 06/23/2008 Page 21 of 22

30. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and

satisfaction.

31. Plaintiff's claims are barred in whole or part because they have been filed in an

improper venue.

32. The Answering Defendants reserve their rights to modify, clarify, amend or

supplement these Additional Defenses as discovery proceeds in this action.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the Answering Defendants demand a trial

by jury as to all issues so triable.

WHEREFORE, Answering Defendants pray that Plaintiff's Complaint against them be

dismissed; that Answering Defendants be granted costs, fees and expenses incurred herein; and

that Defendants be granted such other relief as the Court may deem just and proper.

SANOFI-AVENTIS U.S. INC.

SANOFI-SYNTHELABO INC.

By: s/ Sara J. Gourley_

One of Their Attorneys

Dated: June 23, 2008

Sara J. Gourley

James R.M. Hemmings

SIDLEY AUSTIN LLP

One South Dearborn Street

Chicago, Illinois 60603

(312) 853-7000

sgourley@sidley.com

jhemmings@sidley.com

21

CERTIFICATE OF SERVICE

I hereby certify that of the 23d day of June, 2008, I caused to be served a true and correct copy of the foregoing document by United States mail, postage prepaid on the following counsel of record:

Scott A. Kogen, Esq. Law Offices of Scott A. Kogen & Associates, P.C. 134 N. LaSalle Street, Suite 1515 Chicago, Illinois 60602

Attorney for Plaintiff

s/ James R.M. Hemmings
James R.M. Hemmings